

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION)	MDL 2804
OPIATE LITIGATION)	
)	Case No. 1:17-md-2804
THIS DOCUMENT RELATES TO:)	
)	Judge Dan Aaron Polster
<i>The Montgomery County Board of County</i>)	
<i>Commissioners, et al. v. Cardinal Health, Inc.,</i>)	<u>OPINION AND ORDER REGARDING</u>
<i>et al.,</i>)	<u>KROGER'S MOTION TO EXCLUDE</u>
Case No. 1:180-op-46326)	<u>OPINIONS OF DR. JACK E. FINCHAM</u>
("Track Seven"))	
)	

Defendant Kroger moves to exclude the opinions of Plaintiff's Expert Witness, Jack E. Fincham (docket no. 5070). Plaintiff Montgomery County filed a response (docket no. 5099) and Kroger filed a reply (docket no. 5124). For the reasons stated below, Kroger's motion is **DENIED**.

Dr. Fincham and his Report

Plaintiff retained Dr. Fincham to "[1] review and analyze the Ohio Board of Pharmacy's ["BOP's"] 2020 and 2021 pharmacy workload surveys [the "Surveys"] and [2] the expert report submitted by Dr. J. Ann Selzer on behalf of The Kroger Company." Fincham Rpt. at 4 (docket no. 5070-5). Dr. Fincham is Dean Emeritus and Professor at the University of Kansas School of Pharmacy in Lawrence, Kansas. He has taught fifteen graduate level courses, including Research Design and Methods at four major colleges and universities in the United States. Fincham Dep. at 24:14-26:2 (docket no. 5070-6); Fincham Rpt. at 1-3. Dr. Fincham is the author or editor of thirteen books and has published 255 papers in refereed journals on topics such as pharmacy, public health, health outcomes, and pharmacoepidemiology. Fincham Rpt. at 1-3. Seventy of these publications have been based on questionnaire and survey research. *Id.* Two of Dr.

Fincham's articles on survey research and methods have been cited some 1,500 times by other authors. *Id.*

Dr. Fincham's expert report consists of opinions about the BOP Surveys and also responds to Dr. Selzer's expert report, which criticized certain aspects of the Surveys. In relevant part, Dr. Fincham's report includes the following opinions:

- In my opinion, the Ohio Board of Pharmacy surveys collected sufficient and reliable information from those Ohio pharmacists working in large chain grocery store settings that, when placed in the context of the opioid epidemic, identify serious concerns about the safe and effective dispensing of opioids among other medications. Fincham Rpt. at 5.
- In my opinion, the response rate for pharmacists responding to the 2020 and 2021 survey was adequate and appropriate. Similar surveys assessing the status of the work environment for pharmacists have been conducted with similar response rates. *Id.* at 10
- It is misleading to suggest that only literal questions and answers about opioids can yield insights into the role of pharmacists and opioid abuse.... A complete analysis includes interpreting the survey results and pharmacists' comments in the context of pharmacy practice, policy, and regulations imposed on pharmacists, which Dr. Selzer was not asked or qualified to perform. And yet, doing so, offers obvious insights into how pharmacy workloads impact the safe dispensing of controlled substances, including opioids. *Id.* at 12.
- The survey did not need to gather a representative view of all Ohio pharmacists for the Board to act, and Dr. Selzer assumed a purpose for the survey for which it was not intended. *Id.* at 13.
- In my view, the dispensing requirements and subsequent impact upon opioid dispensing and required monitoring are inherent in any consideration of the workload impact and stresses for pharmacists. *Id.* at 23.
- In my opinion, the 2020 and 2021 pharmacy workload surveys conducted by the Ohio Board of Pharmacy are valid and reliable. Tasked with regulating the practice of pharmacy and following the growing concerns of work conditions, the Board sought to collect and analyze survey responses to highlight whether pharmacy metrics continue to create unsafe work environments. *Id.* at 30.
- The surveys utilized appropriate survey design and research techniques and methodology consistent with the Board's goals. *Id.*

The BOP Surveys⁶

In July of 2020, prompted by concerns among regulators about working conditions in Ohio pharmacies, the BOP conducted a survey to “capture feedback on pharmacist working conditions in the state.”⁷ In April 2021, the BOP issued a report on the 2020 Survey (the “Report”) announcing its findings and conclusions; the Report also disclosed the creation of a Pharmacist Workload Advisory Committee, the purpose of which was to “promote patient safety and compliance with Ohio laws and rules by analyzing survey and other data and make recommendations to the Board to address pharmacist working conditions.” BOP Rpt. (docket no. 5070-1). In 2021, the BOP conducted a follow-up survey to collect “the most up-to-date data.”⁸

The Surveys each asked 16 questions to be answered on a five-step “Likert” scale from Strongly Agree to Strongly Disagree. Each Survey also included a seventeenth question soliciting open-ended narrative feedback related to the general subject areas of the Survey.⁹ The questions focused on workload, staffing, performance metrics, and patient safety. Notably, none of the questions made any specific mention of the dispensing of opioids or other controlled substances; rather, they addressed the pharmacists’ dispensing responsibilities related to all pharmaceuticals.

⁶ In its Track Three Evidentiary Order regarding motions in limine (docket no. 3967), the Court cast grave doubts on the admissibility of the 2020 Survey and the BOP’s 2021 Report discussing the results. The Court declined, however, to exclude the Report and the Survey because it concluded there might be some permissible use of the Report and Survey at trial, despite concerns about their character as hearsay. *See In re Nat’l Prescription Opiate Litig.*, 2021 WL 4341317 at *8-10 (N.D. Ohio Sept. 23, 2021). These issues remain and can be addressed by the trial judge at the appropriate time.

⁷ April 2021 letter of Steven W. Schierholt, Executive Director, State of Ohio Board of Pharmacy. (Docket no. 5070-1 at 5).

⁸ 2021 Pharmacist Workload Survey (docket no. 5070-3 at 2).

⁹ The questions asked in the 2021 Survey were substantially similar to those asked in the 2020 Survey.

The BOP disseminated the Surveys to all pharmacists in Ohio, rather than to a curated sample. Specifically, in 2020, the BOP sent the Survey electronically to 11,588 Ohio pharmacists and received 4,159 responses, for a response rate of 26.41%.¹⁰ In 2021, 14,759 Ohio pharmacists received the Survey and 2,969 responded (20.11%).¹¹ The BOP notified the pharmacists that completion of the Surveys was voluntary and all responses would remain anonymous.

Dr. Seltzer's Report

Kroger engaged Dr. Selzer to review the 2020 Survey, opine on its methodology and reliability, and provide her opinion on “the usefulness of this survey in understanding the role of pharmacists and pharmacies in opioid use and diversion.” Selzer Dep. at 9:19–10:7 (docket no. 5099-1); Selzer Rpt. at 2 (docket no. 5070-4). Dr. Selzer opined that the Surveys’ findings are not relevant to the issues in this case, because the questions posed to the pharmacists asked about dispensing practices generally and did not specifically reference the dispensing of opioids. Selzer Rpt. at 2-3 (docket no. 5070-4). Dr. Selzer also criticized the Surveys for certain methodological deficiencies – most notably, that the Survey results were not necessarily generalizable to the full universe of Ohio Pharmacists, nor to Pharmacists working in Kroger stores. Specifically, Dr. Selzer opined as follows:

- We cannot say that the findings reflect the views of **all** pharmacists licensed and working in Ohio on opioid abuse and diversion or how their work does or does not affect what is happening with opioid abuse. Selzer Rept. at 16 (emphasis added).
- We cannot say the findings reflect the views of **all** pharmacists licensed and working in large chain-grocer/big box stores in Ohio on opioid abuse

¹⁰ Schierholt letter (docket no. 5070-1 at 5).

¹¹ 2021 Pharmacist Workload Survey (docket no. 5070-3 at 3).

and diversion or how their work does or does not affect what is happening with opioid abuse. *Id.* (emphasis added).

- We cannot say the findings reflect the views of **all** pharmacists licensed and working in pharmacies in Ohio owned by The Kroger Co. on opioid abuse and diversion or how their work does or does not affect what is happening with opioid abuse. *Id.* (emphasis added).

Legal Standard

The Court incorporates by reference the applicable *Daubert* legal standards set forth in its *Track One Daubert Order Regarding Dr. Meredith Rosenthal* at 1–10 (docket no. 2495).¹²

Analysis

Kroger argues that Dr. Fincham’s opinions concerning the purpose of the Surveys and the methodology underlying them are unreliable for three separate reasons, each addressed below. Kroger asks the Court to exclude Dr. Fincham’s opinions in their entirety and prohibit him from testifying at trial. Motion at 11. The Court declines this request.

A. Dr. Fincham’s Opinions about the Surveys’ Relevance to the Dispensing of Opioids in Ohio Pharmacies.

Kroger first argues that Dr. Fincham makes contradictory claims about the Surveys’ applicability to the dispensing of opioids, and that those contradictory claims render his opinions unreliable. Motion at 6-8; Reply at 3-4. While Dr. Fincham agrees with Dr. Selzer that the Surveys did not purport to measure pharmacists’ concerns about opioids specifically, he opines in his report that the data generated by the Surveys, “when placed in the context of the opioid epidemic, identify

¹² *In re Nat’l Prescription Opiate Litig.*, 2019 WL 3934597, at *1-5 (N.D. Ohio Aug. 20, 2019).

serious concerns about the safe and effective dispensing of opioids among other medications.” Motion at 7; Fincham Rpt. at 5.

Plaintiff denies these two statements are contradictory. Plaintiff asserts that what the Surveys explicitly measured (concerns about dispensing generally) also sheds light on the conditions in which Ohio pharmacists dispense opioids. Response at 10-11. Plaintiff further argues that Dr. Fincham’s statements can only be understood as contradictory if “concerns about safe dispensing of medication generally would somehow *not* apply to the dispensing of highly dangerous drugs such as opioids.” *Id.*

The Court easily agrees with Plaintiff. It is rudimentary that, if dangerous conditions surrounding dispensing of drugs prevail in Ohio pharmacies generally, those conditions necessarily effect the dispensing of the subset of those drugs that are opioids.

B. Dr. Fincham’s Statements Concerning the Generalizability of the Surveys’ Findings.

Kroger next argues Dr. Fincham’s opinions concerning the generalizability of the Surveys’ findings are “unreliable and unhelpful to the trier of fact” and should, therefore, be excluded. Motion at 10-11. Kroger cites this opinion of Dr. Selzer:

The point of conducting any survey is to use answers from relatively few members of the meaningful universe under study to reflect all who meet the criteria of that meaningful universe in the real world. In other words, the investigator wants to make claims about the [entire relevant] population using data from a sample. They want to generalize the findings beyond just those who participated in the survey.

Selzer Rpt. at 15.

Dr. Selzer likened statistical sampling to a stew, where a well-designed sample is like a well-stirred pot: “You don’t have to eat the entire pot, but you need to pull a representative spoonful from a well-stirred pot.” Selzer Dep. at 173:12-20. Dr. Selzer pointed out that the

designers of the Surveys did not select a sample of the universe of Ohio pharmacists, but rather sent the Surveys to all Ohio pharmacists and analyzed the responses of the roughly 20-25% of recipients who choose to complete and submit the Surveys. Selzer Rpt. at 15. Dr. Selzer concluded that, as a result of the absence of sampling and the modest response rate, the data generated by the Survey cannot be generalized to “reflect the views of all” Ohio pharmacists who work in large chain-grocer/big box stores or of those who work in Kroger pharmacies. *Id.* at 16.

Kroger further asserts Dr. Fincham contradicted himself in his report and deposition testimony on the subject of generalizability. Motion at 10-11. Kroger notes that, in his deposition, Dr. Fincham stated “[t]he survey wasn’t [meant] to do any kind of generalization” and indicated that extrapolating the results of the Surveys to all pharmacies was not the purpose of the study. Fincham Dep. at 120:16-24; 148:22–149:7. Kroger then points to a passage from Dr. Fincham’s report stating that “[d]ata from the surveys indicates that pharmacists working in large chain grocery stores believe their employers’ policies and procedures, workload tasks, metrics and staffing levels in their workplace impact patient safety” Fincham Rpt. at 30. Kroger maintains these ostensibly contradictory statements about the generalizability of the Surveys’ findings render his opinions unreliable and inadmissible. Motion at 10-11; Reply at 7-9.

In response, Plaintiff notes Dr. Fincham’s report and his deposition testimony downplayed the importance of generalizability in assessing the value of the Surveys. Dr. Fincham’s report states the BOP “conducted its surveys to gather information about existing workload concerns that required further study, and not necessarily to understand what **all** Ohio pharmacists believed.” Fincham Rpt. at 8 (emphasis added). Dr. Fincham explained that the Board of Pharmacy carried out the Surveys to elicit “a general sense of workplace conditions that impacted patient safety in the practice of pharmacy in these settings in Ohio.” Response at 15; Fincham Dep. at 42:20–43:14,

51:8–53:14, 74:4–11; Fincham Rpt. at 9. Put differently, the BOP conducted its surveys to see if and where workload concerns existed generally, not to determine whether *all* pharmacists had such concerns. In any event, Plaintiff stresses that Dr. Fincham addressed the validity of the Surveys by pointing to similar surveys conducted by other states and the American Pharmacist Association, each of which yielded comparable responses. Response at 14, Fincham Rpt. at 25–28.

The Court is not at all persuaded that any perceived contradiction in Fincham’s positions on generalizability renders his report or testimony so unreliable as to justify barring his testimony. Having carefully reviewed all of Dr. Fincham’s deposition testimony, the Court appreciates Dr. Fincham’s explanation that the Surveys’ design was a function of the BOP’s purpose and intent in conducting them. Dr. Fincham, an expert in research design and methods, explained that the purpose of the BOP in conducting the Survey was to gather information about the work environment in order to inform a policy plan that included further investigation. Fincham Dep. At 43:15–44:2. The purpose was not to predict what *all* pharmacists believe, but rather to get a sense of the work environment in which they practice. Dr. Fincham explained that, in his experience, a 20% response rate for such a “field study” was typical of similar studies and did not raise concerns about generalizability, for the results were not intended to be wholly generalizable.²¹ Should Plaintiff ultimately call Dr. Fincham to the witness stand, Kroger is free to cross-examine him to reveal any flaws or contradictions in his testimony. *See Daubert*, 509 U.S. at 596 (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”).

²¹ Fincham Dep. at 44:3 – 45:6; 58:17 – 62:1. Dr. Fincham described a field study as one that is “conducted as a general assessment of what factors are in an environment.” *Id.* at 60:9–20.

C. Dr. Fincham's Methodology

Finally, Kroger argues the Court should exclude Fincham's opinions because he does not provide "any statistical analysis of the Pharmacist Workload Surveys' data in support of his assertion that the data 'identifies serious concerns about the safe and effective dispensing of opioids'" Motion at 8-9. Kroger suggests Dr. Fincham relies solely on his *ipse dixit* to connect his conclusions with the Survey data. Kroger contends Dr. Fincham's testimony will confuse the jury. Reply at 7. Kroger insists that "*Daubert's* reliability threshold requires an expert to analyze survey data in accordance with accepted statistical principles." *Navarro v. Procter & Gamble Co.*, No. 1:17-CV-407, 2021 WL 868586, at *15 (S.D. Ohio Mar. 8, 2021) (internal citations omitted).

Plaintiff denies that Dr. Fincham relies solely on his *ipse dixit* and maintains he does, in fact, employ a methodology – the very same methods he uses in his academic research, as he described in his report and deposition. Plaintiff also argues *Navarro* does not apply here, where the expert is not the one who conducted the survey, but merely analyzed its conclusions and methods. Response at 12-13.

Although Dr. Fincham may not have engaged in a formal statistical analysis of the Surveys, the Court is satisfied his opinions are sufficiently grounded in appropriate research methods to survive Kroger's reliability challenge under *Daubert*. Dr. Fincham explained in his report that his opinions are based on his research and publications in survey design, among other things. Fincham Rept. at 4. And when asked about his methodology during his deposition, Dr. Fincham responded that he employed, for example, the methodologies described by Dr. Donald Dillman in "The Total Design Method," a text on research methods that Dr. Fincham described as "the gold standard reference point" for research methodologies. Fincham Dep. at 176:8–178:6. Given Dr. Fincham's

extensive record of publications on survey research, the Court has no trouble finding that his opinions are sufficiently grounded in accepted research methods to satisfy *Daubert*'s reliability standard. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 590 at 593-94 (1993) (the trial court should consider as a factor "whether the theory or technique . . . has been subjected to peer review and publication); *see also Kumho Tire Co., Ltd. v. Charmichael*, 526 U.S. 137 at 152 (1999) (the reliability inquiry asks whether the expert, "basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field").

The Court agrees with Plaintiff that *Navarro* is inapposite, as the court there was assessing the reliability of the defendant's expert who was the proponent of his own surveys. Consequently, the court was scrutinizing the methodology by which the expert had designed and conducted his surveys. The analogous inquiry here – whether the Surveys are sufficiently reliable to be admissible – is not before the Court in the present motion. Moreover, while the *Navarro* court found some merit in the plaintiff's criticisms of the expert's methodology, it ultimately concluded that any flaws in his methodology went to the weight of the evidence, not its admissibility. The same conclusion applies here. *See Ruiz-Trioche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998) (quoting *Daubert*, 509 U.S. 590) ("As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process – competing expert testimony and active cross examination – rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.").

Conclusion

For the reasons stated above, Kroger's Motion is **DENIED**. As the Court explained in its Track Three Evidentiary Order regarding motions in limine,²³ the admissibility of the Surveys will depend upon the use to which Plaintiff seeks to put them. Docket no. 3967 at 16-18. The same is true of Dr. Fincham's testimony. Plaintiff might be able to offer Dr. Fincham's testimony, for example, to demonstrate that the Surveys' design reflects the purposes for which the BOP intended to use them, but not to demonstrate that the Surveys' findings are representative of the views of *all* pharmacists, or of *all* pharmacists in chain grocery settings, or of *all* Kroger pharmacists, or perhaps even of *any* Kroger pharmacists. Should Plaintiff ultimately call Dr. Fincham to the witness stand, Kroger will be free to cross-examine him to reveal any flaws or contradictions in his opinions. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

IT IS SO ORDERED.

s/ Dan Aaron Polster August 18, 2023
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

²³ *In re Nat'l Prescription Opiate Litig.*, 2021 WL 4341317 (N.D. Ohio Sept. 23, 2021).